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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,707	11/24/2003	Henry Daniell	1202-CON2-DIV-00	5370
22469	7590	03/01/2005	EXAMINER	
SCHNADER HARRISON SEGAL & LEWIS, LLP 1600 MARKET STREET SUITE 3600 PHILADELPHIA, PA 19103			FOX, DAVID T	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/720,707	DANIELL ET AL.	
	Examiner	Art Unit	
	David T. Fox	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 5/17/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/11/04</u> | 6) <input type="checkbox"/> Other: _____ |

In response to Applicant's arguments in the election of 07 December 2004, the Examiner has WITHDRAWN the outstanding restriction requirement. Claims 21-40 are examined in the Office action that follows.

The application should be reviewed for errors. Errors appear, for example, on page 3 of the specification, line 21, where "Kline" should be replaced with ---Klein--- (as correctly recited on page 14 of the specification, line 33); on page 5 of the specification, line 5, where ---origin--- is misspelled; on page 6, line 27 where "neumann" should be capitalized; on page 7, lines 26 and 37, where "geirite" should be replaced with ---gelrite---; on page 8, line 25, where "2' " should be replaced with ---3' --- (as correctly recited on page 11, lines 19 and 24); on page 11, line 2 where ---identified--- is misspelled; on page 15, line 33, where "dic" should be replaced with ---dicots---; and on page 16, line 38, where "were" should be replaced with ---where---.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an application data sheet by identifying the prior application by application number (37 CFR 1.78(a)(2) and (a)(5)). If the prior application is a non-provisional application, the specific reference must also include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

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Specifically, page 1 of the specification should be amended to recite all of the continuity data presented in the corrected Application Data Sheet of 22 December 2003. Additionally, the issued status of parent application 10/223,160 as U.S. 6,680,426 should be recited.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-22, 25-28, 33-34 and 37 of U.S. Patent No. 5,932,479. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the vector and expression cassettes comprising a chloroplast functional promoter including the psbA, rbcL or atpB promoters operably linked to a coding sequence encoding a desired peptide, which coding sequence is operably linked to a transcription terminator sequence, further comprising a selectable marker gene, and flanked by chloroplast DNA regions of homology, and chloroplasts transformed therewith, as claimed in the patent; to obtain the the vector and expression

cassettes comprising a chloroplast functional promoter including the psbA, rbcL or atpB promoters operably linked to a coding sequence encoding a desired peptide, which coding sequence is operably linked to a transcription terminator sequence, further comprising a selectable marker gene, and flanked by chloroplast DNA regions of homology, and chloroplasts transformed therewith, as claimed in the instant application. The claims are coextensive.

Claims 21-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,680,426. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the plant cells comprising chloroplasts transformed with the vector and expression cassettes comprising a chloroplast functional promoter operably linked to a coding sequence encoding a desired peptide, which coding sequence is operably linked to a transcription terminator sequence, further comprising a selectable marker gene, and flanked by chloroplast DNA regions of homology, as claimed in the patent; to obtain the chloroplasts transformed with the vector and expression cassettes comprising a chloroplast functional promoter including the psbA, rbcL or atpB promoters operably linked to a coding sequence encoding a desired peptide, which coding sequence is operably linked to a transcription terminator sequence, further comprising a selectable marker gene, and flanked by chloroplast DNA regions of homology, as claimed in the instant application. The claims are coextensive.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29, 36 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29 and 36 are indefinite in their recitation of "the *rRNA* promoter" which implies that there is only one promoter of this class, which contradicts the teaching in the specification on page 10, line 31 that there are many "*rRNA* promoters" from many different *rRNA* genes. See also Sugita et al submitted by Applicant, page 316, Table 1, which lists at least two *rRNA* genes, namely the 16S and 23S *rRNA* genes.

Replacement of "the" before "*rRNA*" in claims 29 and 36 with ---an--- would obviate this rejection.

Claim 36 is indefinite in its recitation of improper Markush terminology.

Replacement of "or" in line 2 with ---and--- would obviate this rejection. See MPEP 2173.05(h).

Claim 40 is indefinite in its recitation of "taken from a gene wherein expression is regulatable by light" as it is unclear whether the light-regulatable expression occurs in the native gene source or in the expression cassette, i.e., it is unclear what phrase is modified by "expression".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21, 23, 34 and 39-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 21 and 39-40 are broadly drawn to chloroplast-functional expression cassettes comprising any non-promoter 5' untranslated region of any sequence and from any source. Claims 21, 34 and dependents are also broadly drawn to any promoter from any non-chloroplast or even non-plant gene, given their recitation of "promoter region from a gene capable of expression in the plant chloroplast", since any coding sequence is capable of expression in a plant chloroplast if it is operably linked to a chloroplast-functional promoter.

In contrast, the specification only provides guidance for chloroplast-functional expression cassettes comprising an entire chloroplast-functional promoter. No guidance is provided for any non-chloroplast promoter or non-promoter 5' untranslated region which somehow effects transcription in plant chloroplasts, and no guidance is provided for any conserved sequences among this broad genus which are correlated with the function of effecting transcription in plant chloroplasts.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v.*

Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Claims 21, 23, 34 and 39-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 21 and 39-40 are broadly drawn to chloroplast-functional expression cassettes comprising any non-promoter 5' untranslated region of any sequence and from any source. Claims 21, 34 and dependents are also broadly drawn to any promoter from any non-chloroplast or even non-plant gene, given their recitation of "promoter region from a gene capable of expression in the plant chloroplast", since any coding sequence is capable of expression in a plant chloroplast if it is operably linked to a chloroplast-functional promoter.

In contrast, the specification only provides guidance for chloroplast-functional expression cassettes comprising an entire chloroplast-functional promoter. No guidance is provided for any non-chloroplast promoter or non-promoter 5' untranslated region which somehow effects transcription in plant chloroplasts, and no guidance is provided for any conserved sequences among this broad genus which are correlated with the function of effecting transcription in plant chloroplasts.

The expression of transgenes in plant chloroplasts is unpredictable, particularly when under the control of non-chloroplast promoters or non-promoters. Ye et al teach that heterologous GUS gene expression was not observed in the chloroplast when the non-chloroplast CaMV 35S promoter was used (see, e.g., page 811, Figure 1 and paragraph bridging the columns; page 812, column 2, bottom paragraph). Sugita et al (submitted by Applicant) teach the unique features of the regulation of chloroplast gene expression, including the unique structural features of chloroplast promoters which distinguish them from other promoters, wherein even among the genus of chloroplast promoters, not all of the structural features are conserved (see, e.g., pages 315- 316, paragraph bridging the columns of each page). See also Blowers et al (1990), who teach that even among chloroplast promoters, one third of those tested showed extremely low frequencies of heterologous gene expression, and that there is a lack of understanding of the necessary elements for successful promoter function in chloroplasts (see, e.g., page 1064, column 1, third paragraph; page 1067, column 1, top paragraph).

Furthermore, the functions of 5' and 3' untranslated regions of chloroplast genes are unpredictable in their own right, independent of whether promoters are additionally present or not. Thus, it is unpredictable that a promoter-less 5' untranslated region would function by itself to effect gene expression in the chloroplast, either at all or at levels sufficient to effect a phenotypic change or to produce substantial quantities of a desired product. In the absence of either of these conditions, no use has been disclosed for transformed chloroplasts.

Maliga et al (U.S. 5,877,402) teach that transcription efficiencies are not correlated with translation efficiencies of 5' untranslated regions of chloroplast genes, and that the downstream coding sequence may also have an effect (see, e.g., column 64, lines 21-55). Eibl et al also teach that 5' untranslated regions differ with respect to their abilities to enhance transcription versus translation, and that only a single 5' untranslated region, namely that from the *psbA* gene, was able to effect light regulation, as claimed in instant claim 40. See, e.g., page 333 of Eibl et al, Abstract.; page 334, column 2, bottom two paragraphs; page 335, Table 1; paragraph bridging pages 335 and 336; page 337, Table 2; page 338, paragraph bridging the columns; paragraph bridging pages 338 and 339; page 339, paragraph bridging the columns; paragraph bridging pages 340 and 341; page 341, column 2, bottom two paragraphs). Fargo et al teach that mutations predicted to strengthen the secondary structure of the *rps7* 5' untranslated region actually decreased reporter gene expression (see, e.g., page 6980, Abstract; page 6981, column 1, top paragraph). Kuroda et al teach that overexpression of a particular 5' untranslated region resulted in a toxic chlorotic phenotype, so that it is

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unclear how to make and use viable plant cells transformed with expression cassettes encoding any and all 5' untranslated regions (see, e.g., page 1600, Abstract).

Furthermore, the 3' untranslated region may unpredictably exert its own influence on heterologous protein accumulation, thus further confounding the situation (see, e.g., Monde et al, page 529, Abstract; paragraph bridging pages 533 and 535; page 537, column 2; paragraph bridging pages 538 and 539).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate a multitude of non-exemplified non-chloroplast or non-plant promoter types, or a multitude of non-exemplified promoterless 5' untranslated regions, for their ability to effect expression of heterologous coding sequences in transformed chloroplasts, particularly at levels high enough to effect phenotypic change or production of desired product, or in the absence of deleterious effects to plant health.

The claims are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest a chloroplast-functional expression cassette comprising a chloroplast functional promoter operably linked to a coding sequence encoding a desired peptide, which coding sequence is operably linked to a transcription terminator sequence, further comprising a selectable marker gene, and flanked by chloroplast DNA regions of homology; or chloroplasts or plant cells transformed therewith; as stated in the allowed parent applications.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795.

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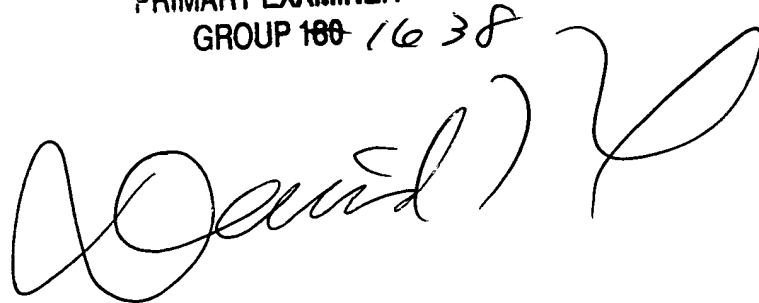
The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy J. Nelson, Ph.D., can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 27, 2005

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in black ink, appearing to read "David T. Fox", with a large, stylized flourish extending to the right.